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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,125	07/08/2003	Axel Grandt	JM-040	2218
7590 Nicola A. Pisano, Esq. Suite 200 11988 El Camino Real San Diego, CA 92130			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 04/15/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/616,125

Applicant(s)

GRANDT, AXEL

Examiner

Brian E. Pellegrino

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 9, 10, 13, 14, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-8, 12, 15-18, 21-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This claim depends from a canceled claim, thus it does not further limit any claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,5,6,12,15-18,21-23,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tower et al. (EP 1057460) in view of Globerman et al. (WO 96/26682) and Brown et al. '305. Tower discloses (Fig. 2) a plurality of circumferential rings affixed together to form the stent. Tower also discloses that the rings are formed from wire shaped into sinusoidal bends, col. 4, lines 55-58 and col. 5, lines 33-39. Tower discloses implanting the stent in a blood vessel, paragraph 36. However, Tower fails to disclose the circumferential rings of tubular member material being provided with pores and a lumen to contain a therapeutic material for delivery to a treatment site. Globerman et al. teach (Fig. 5) a tubular material **14** used as a stent with a lumen **16**. Globerman also teaches the stent tubular member can include a multiplicity of pores in

fluid communication with the lumen (page 7, lines 11-15) for a therapeutic agent disposed within the lumen to be eluted from the stent. Brown et al. teach (Fig. 2) a stent with circumferential sections including a channel **20** for therapeutic material. Brown discloses that bioabsorbable polymers (col. 8, lines 62-65, col. 9, line 1, col. 10, lines 19-21) are used as means for controlling release from the channel into the lumen of the patient. It would have been obvious to one of ordinary skill in the art to incorporate a lumen with a absorbable polymer having a drug disposed in the tubular members forming the circumferential rings of Tower's stent per the teachings of Globerman and Brown. The modification provides the doctor the ability to treat the patient locally at a diseased or stenosed region in a patient's blood vessel. Regarding claim 25, Tower discloses individual circumferential rings and modifying with Globerman and Brown is to only make the rings hollow and contain therapeutic material.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tower et al. (EP 1057460) in view of Globerman et al. (WO 96/26682) and Brown et al. '305 as applied to claim 1 above, and further in view of Harry (2002/0038146). Tower as modified by Globerman and Brown is explained supra. Brown does disclose the pores can be any type of opening or shape, col. 6, lines 15-18. However, Tower in view of Globerman and Brown fail to disclose the pores vary in size or shape with respect to one another. Harry teaches (Figs. 2,3) pores varying in size on the stent. Harry also teaches (Fig. 8) pores that vary in shape on the stent. It would have been obvious to one of ordinary skill in the art to vary the size or shape of the pores as taught by Harry

with the stent of Brown to provide different amounts of therapeutic material released from the stent.

Response to Arguments

Applicant's arguments filed 1/9/08 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). First, the Applicant attempted to argue that Tower is teaching away from the Brown and Globerman stent teachings by not being hollow and alleging Tower's stent is thin. The Examiner would like to note that "thin" is a relative term and depends on what things are being compared to determine what may describe an object. All the stents of record can be considered to be "thin" since the area of application of these devices is such a small location, that it is highly unlikely that one would consider the stents of Brown and Globerman to be thick stents. The Examiner is not persuaded. It appears that the Applicant has misunderstood the rejection or failed to appreciate the Examiner's position that the modification of Tower (having the same structure for the stent framework or layout as claimed) is modified by Globerman and Brown to improve the

stent capabilities by incorporating therapeutic material into a modified hollow set of rings. Drug delivery is well known in the art whether it is for antithrombogenic purposes, antiangiogenic or for preventing infection or treatment of diseased areas, etc. the incorporation of therapeutic material is an obvious expedient. The Examiner was not attempting to create an "obvious to try" invention, but using known teachings when combined together produce a stent that has predictable results.

With respect to the rejection over Tower et al. in view of Globerman et al. and Brown et al. and further in view of Harry, the Examiner would like to note that motivation was provided. Second it is common sense that larger holes as result of size and shape would release more drug or therapeutic material from a pore. Smaller holes in size and shape would release less therapeutic agents. Thus, it is clearly desirable to modify the size and shape as taught by Harry to produce predictable results and only involve routine skill in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/
Primary Examiner, Art Unit 3738